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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,328	06/13/2005	Jun Kuai	WYTH-P01-001	8048

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EXAMINER	
EMCH, GREGORY S	

ART UNIT	PAPER NUMBER
1649	

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08/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/523,328	KUAI ET AL.	
	Examiner	Art Unit	
	Gregory S. Emch	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12,17,22-25,33-37,39 and 44-56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-12,17,22-25,33-37,39 and 44-56* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Claim 56 has been amended and claims 13-16, 18-21, 26-32, 38, 40-43 and 57 have been canceled as requested in the preliminary amendment filed on 01 February 2005. Following the amendment, claims 1-12, 17, 22-25, 33-37, 39 and 44-56 are pending in the instant application.

Claims 1-12, 17, 22-25, 33-37, 39 and 44-56 are under examination in the instant office action.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-12, 17 and 22-25, is drawn to an isolated, purified, or recombinant protein complex comprising: (i) a tumor necrosis factor alpha (TNF-α) polypeptide or a functional variant thereof; (ii) a TNF-α receptor (TNFR) polypeptide or a functional variant thereof; and (iii) at least one polypeptide selected from the group consisting of: NF-κB activating kinase (NAK), RasGAP3, TRCP 1, TRCP2 and a functional variant thereof.

Group II, claim(s) 33-36, is drawn to a host cell comprising a first nucleic acid, a second nucleic acid and a third nucleic acid, wherein the first nucleic acid comprises a recombinant nucleic acid encoding a TNF-α polypeptide, wherein the second nucleic acid comprises a recombinant nucleic acid encoding a TNFR polypeptide and wherein

the third nucleic acid comprises a recombinant nucleic acid encoding a polypeptide selected from the group consisting of: NAK, RasGAP3, TRCP 1, and TRCP2.

Group III, claim(s) 37 and 39, is drawn to an assay for identifying a test compound which inhibits or potentiates the stability of a complex, comprising: (a) forming a reaction mixture including: (i) a TNF-α polypeptide; (ii) a TNFR polypeptide (iii) at least one polypeptide selected from the group consisting of: NAK, RasGAP3, TRCP1, and TRCP2; and (iv) a test compound; and (b) detecting the presence of TNF-α or TNFR in the complex.

Group IV, claim(s) 44 and 45, is drawn to a method for modulating, in a cell, a protein complex comprising at least a first protein and a second protein, wherein said first protein is TNFR, and wherein said second protein is selected from the group consisting of: NAK, RasGAP3, TRCP 1, and TRCP2, said method comprising: administering to said cell a compound capable of modulating said protein complex.

Group V, claim(s) 46 and 47, is drawn to a method of producing a functional complex comprising: (i) transfecting a cell with a polynucleotide encoding a polypeptide selected from the group consisting of: NAK, RasGAP3, TRCP1, and TRCP2; (ii) contacting said cell with a TNF-α polypeptide; (iii) thereby forming a complex.

Group VI, claim(s) 48 and 49, is drawn to a method for treating a TNF-α-related disorder, by administering an effective amount of a compound that inhibits the interaction of TNF-α or TNFR with a polypeptide selected from the group consisting of: NAK, RasGAP3, TRCP1, and TRCP2.

Group VII, claim(s) 50-52, is drawn to a method of identifying a test compound that is a candidate modulator of inflammation or apoptosis, the method comprising: (i) forming a mixture comprising a TRCP1 polypeptide or a variant polypeptide thereof, and a test compound; and (ii) measuring the interaction between the TRCP1 polypeptide or the variant and the test compound.

Group VIII, claim(s) 53-55, is drawn to a method of identifying a test compound that is a candidate modulator of inflammation or apoptosis, the method comprising: (i) forming a mixture comprising a TRCP2 polypeptide or a variant polypeptide thereof, and a test compound; and (ii) measuring the interaction between the TRCP2 polypeptide or the variant and the test compound.

Group IX, claim(s) 56, is drawn to a method of treating a TNF-α-related disease, which includes an inflammatory, or apoptotic component, by administering an effective amount of a therapeutic composition that modulates TRCP1.

Group X, claim(s) 56, is drawn to a method of treating a TNF-α-related disease, which includes an inflammatory, or apoptotic component, by administering an effective amount of a therapeutic composition that modulates TRCP2.

The inventions listed as Groups I-X do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical feature linking Groups I-X is that they all relate to an isolated, purified, or recombinant protein complex comprising: (i) a tumor necrosis factor alpha (TNF-α) polypeptide or a functional variant thereof; (ii) a TNF-α receptor (TNFR) polypeptide or a functional variant thereof; and (iii) at least one polypeptide selected from the group consisting of: NF-κB activating kinase (NAK), RasGAP3, TRCP 1, TRCP2 and a functional variant thereof. However, Heyninck et al. (Mol Cell Biol Res Commun. 2001 Sep;4(5):259-65; Cite No. CI on IDS dated 13 June 2005) teaches protein complexes comprising TNF-α, a TNFR and NAK (entire document, e.g., figs. 1 and 2). Thus, the technical feature linking the inventions of Groups I-X does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Polypeptides:

a. NAK

b. RasGAP3

c. TRCP1

d. TRCP2

Applicants are required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicants will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicants must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: 1-12, 17, 22-25, 33-37, 39 and 44-56.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: they are drawn to unique and distinct proteins with independent structure and functions.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

TNF-*α* receptors:

e. TNFR1

f. TNFR2

Applicants are required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicants will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicants must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: 1-12, 17, 22-25, 33-37, 39 and 44-56.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: they are drawn to unique and distinct proteins with independent structure and functions.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Polypeptides:

g. TRADD

h. TRAF2

i. TRAP2

Applicants are required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicants will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicants must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: 1-12, 17, 22-25, 33-37, 39 and 44-56.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or

corresponding special technical features for the following reasons: they are drawn to unique and distinct proteins with independent structure and functions.

Applicants are advised that the reply to this requirement to be complete must include (i) elections of species and invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicants traverse on the ground that the inventions or species are not patentably distinct, applicants should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory S. Emch whose telephone number is (571) 272-8149. The examiner can normally be reached 9:00 am - 5:30 pm EST (M-F).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gregory S. Emch/

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22 August 2007

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